510(k) Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

The assigned 510(k) number is: K112187

Submitter

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Date Prepared:

July 27, 2011

Device name and classification:

- **Device Name:** FM-1000 Plus Fetal Monitor
- **Classification Name:** 884.2740 System, Monitoring, Perinatal
  Product code: HGM
- **Regulatory Class:** Class II

Predicate Device:

Cadence II Fetal Monitor K073221 Manufacturer: EDAN Instruments

Device Description:

FM-1000 Plus Fetal Monitor

The FM-1000 Plus Fetal Monitor can provide different configurations according to different user requirements, FHRI (USI), FHR2 (US2), TOCO, FM (remote marker), AFM (automatic fetal movement mark), fetal stimulator (optional),DECG (direct fetal ECG, optional), and JUP(Intra-uterine Pressure, optional). The user can select the monitors according to requirements. FM-1000 Plus adopts 5.7" LCD, and the collected data, trends, and monitoring parameters are displayed at the same screen. A built-in thermal recorder is used to record the monitoring information.

Intended Use:

The FM-1000 Plus Fetal Monitor is used to monitor fetal well being during the antepartum period what is commonly called the non stress test. It is to be used by trained medical personnel in hospitals, clinics, physician's offices and in the patient's home by prescription or doctors orders.

Effectiveness and Safety Contraindications:

Clinical Test

Clinical testing is not required

Comparison to the predicate device:

The subject device has similar technology characteristics and has the same intended use as the predicate device.

Substantially Equivalent Determination:

Verification and validation testing was done on the FM-1000 Plus Fetal Monitor. This premarket notification submission demonstrates that FM-1000 Plus Fetal Monitor is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Advanced Instrumentations, Inc.
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SEP 2 1 2011

Re: K112187
Trade/Device Name: FM-1000 Plus Fetal Monitor
Regulation Number: 21 CFR 884.2740
Regulation Name: Perinatal monitoring system and accessories
Regulatory Class: II
Product Code: HGM
Dated: September 13, 2011
Received: September 15, 2011

Dear Dr. Millan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name:

FM-1000 Plus Fetal Monitor

Indications for Use:

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Prescription Use _X_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K112187